REMARKS

In accordance with the above amendments, claims 135, 152, 168 have been amended and new claims 183-211 have been added. Thus, claims 135-144, 152-161,168-176 and 183-211 remain in the subject application. No claim has been allowed.

The cancellation of claims 145-151, 162-167 and 177-182 in response to an election requirement has been acknowledged by the Examiner. Any cancellation of claims in this application has been done without disclaimer and applicants specifically reserve the right to pursue any claims canceled in this application in further divisional or continuing applications.

The rejection of claims 135, 152 and 168 under 35 USC § 112, first paragraph, is believed to have been met by the deletion of the language "wherein the polynucleotide is one that does not encode oncogene products" from each of those claims. This has been done in accordance with the Examiner's suggestion and does not represent an admission that this material was, in fact, new matter. It is requested that this rejection be withdrawn.

With respect to the rejection under the non-statutory, judicially created doctrine of double-patenting, it is noted that the conflicting co-pending application No. 10/074,945 is now abandoned thereby rendering the double-patenting issue moot and this should remove that rejection in the present application.

Amendments have been made to independent claims 135, 152 and

168 such that these claims now state that the polynucleotide in the genome of the transgenic animal is "comprised in a virus or virus-derived DNA" and that the "polynucleotide expresses an agent which is of therapeutic benefit for use in human or veterinary medicines or well being or wherein the polynucleotide provides a suitable anatomical or physiological phenotype for human xenograft transplantation".

It should be noted that new claims 183-211 are all further directed to lentiviruses. These new claims closely parallel claims 135-176 in other respects and are clearly supported by material originally found in the application.

The claim rejections on the merits will now be addressed. Applicants have again reviewed Brinster et al (USPN 5,858,354) and Deboer et al (USPN 5,741,957) in light of the present Office Action and the present amendments to the claims. Applicants remain convinced that the present claims are both novel and inventive with regard to the cited references.

In relation to Brinster et al, applicants must reiterate that there is no disclosure that the progeny contain virus derived DNA associated with the transgene. In Brinster et al, the (donor) male mice which are the source of testes cells which are introduced into recipient testes are ones which contain the E. coli lacZ gene (see Examples A and B in columns 12). There is no indication whatsoever that viral vectors have been used and, in

fact, the only way that the progeny are tested to show that they contain a transgene is by staining for β-galactosidase activity.

In contrast, in the presently claimed invention viral DNA is present integrated into the genome.

This is believed to be sufficient to distinguish the present claims from Brinster et al particularly since a key feature of the claimed invention (i.e., that viral vector DNA is present integrated into the genome) is not disclosed or suggested in Brinster et al.

Furthermore, there is no disclosure of lentiviruses in Brinster et al.

In relation to Deboer et al, it should be noted that the transgenic bovines are made using microinjection of pronuclei with plasmids or cosmids (see, for example, Example 7 which appears to make use of the vectors of Examples 4 and 5). Thus, unlike the claimed transgenic non-human animals, the transgenic bovines of Deboer et al do not contain DNA derived from a viral vector integrated into the genome with the polynucleotide encoding the gene product. This, among other reasons, is believed to distinguish the present claims from Deboer et al as with Brinster et al since the same key feature of the claimed invention (i.e., that viral vector DNA is present integrated into the genome) is not disclosed or suggested in Deboer et al either.

Deboer et al also does not disclose lentiviruses.

It is the Examiner's position that the claims lack novelty over Brinster et al and Deboer et al on the basis that "the process steps in the claims do not exclude transgenic animals made by other means since the method steps do not result in a materially different transgenic animal than that produced by the methods of either Brinster et al or Deboer et al".

Applicants believe that the amended claims are novel over Brinster et al and Deboer et al in any event because of the required presence of DNA derived from a viral vector integrated into the genome with the polynucleotide encoding the gene product.

Further with regard to Leder et al (USPN 4,736,866), applicants submit that the amended claims remain patentable over that reference also. It remains that the only transgene product described in Leder et al is an oncogenic product. The only vectors described in Leder et al are MMTV and Rous Sarcoma virus. Neither of these are lentiviruses. Thus, the proposed amended claims remain novel over Leder et al because an oncogene does not express an agent as claimed or provide a phenotype suitable for human xenograft transplantation and Leder et al does not disclose the use of lentiviruses and so their transgenic animals do not contain lentiviruses as claimed.

In view of the above amendments taken together with remarks herein, applicants believe that the present claims inventively

distinguish over the prior art and respectfully request that the Examiner reconsider and withdraw the present rejections and allow the claims.

Respectfully submitted,

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